Risk-Based Monitoring: Phase 1

Process Flow Chart

Senior Management

Decision on the introduction of RBM

Yes → Define RBM Implementation Team composition

No → End process Consider compliance with GCP E6 (R2)

Communicate changes in roles to staff and implement change management team for smooth transition

RBM Implementation Team

Contact the project team, study teams and functional experts to discuss risk areas, such as critical processes, applications, data points, resource requirements

Review documents such as FDA Guidance document, EMA reflection paper, TransCelerate RACT, ISO 31000, MCC RAMMT, publications

Agree upon list of risk areas & requirements for project or study in question and categorize the risks according to the GCP E6R2 / ISO 31000

Communicate status and direction of the project to the entire community / stakeholders

Identify RBM Application Selection Team Members

Identify RBM Process Description Team Members

Dataset of project or study risks

Risk Based Monitoring Process Description Team

Develop SOPs for RBM implementation

Develop task descriptions for roles involved in RBM

Develop training material for RBM processes

Discuss changes in roles with management

Deliver training for affected functions on RBM

The Risk Based Monitoring Application Selection Team

Do we need an RBM application or do we go for a homegrown Excel-based solution ?

With RBM-focused solution → Off the shelf application → Go to Phase 2

With general solution (e.g., Excel, SAS, Spotfire) → Create Excel based sheets and macros → Deliver training for affected functions on RBM

Supportive Information

Consider the following functions for the RBM implementation team:

- Clinical Data Management
- Biostatistics
- Study Management
- Project Management
- Monitoring / Clinical Operations
- Pharmacovigilance
- Stats / CDM Programming
- Information Technology
- Regulatory Affairs
- Clinical Pharmacology
- Bioanalytics / Pharmacokinetics

http://www.fda.gov/downloads/Drugs/Guidances/UCM269919.pdf

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/11/WC500155491.pdf

http://www.iso.org/iso/home/standards/iso31000.htm

http://metricschampion.org/risk-assessment-mitigation-management-tool-rammt-v1-0-102015/

The Risk Matrix- Clinical Study

SEVERITY	CONSEQUENCES			LIKELIHOOD				
	Budget Safety	Study Timelines	Study Budget	1 Very Unlikely	2 Unlikely	3 Possible	4 Likely	5 Very Likely
1	No injury	No effect	No cost	Low	Low	Low	Low	Low
2	Minor injury or inconvenience	Otherwise on-schedule/ minimal effect	Minimal cost	Low	Low	Low	Medium	Medium
3	Moderate injury requiring intervention	Moderate effect on timelines/ milestones	Moderate increase in cost/ resources required to rectification	Low	Low	Medium	High	High
4	Severe injury resulting in permanent damage	Significant effect on all study milestones	Significant increase in study cost requiring management approval	Low	Medium	Medium	High	High
5	Death	Study must be halted or delayed	High financial impact to meet study final study end/ financially feasible	Medium	Medium	High	High	High

SOPs on e.g.:
The general RBM process as part of the overall risk management approach

The development of Key Risk Indicators, their thresholds and the approval process

The adaptation process of on-site monitoring based upon the RBM tool risk findings

The documentation of the findings, the actions taken, the relationship to the CAPA system and the study closure with respect to RBM findings

The Worksheets

RISK	Risk Categories		Risk Owner	Controls	Mitigation Actions	Priority	Comments
Short Description of Risk	Likelihood	Severity of Impact	Individual, Not Function	Existing Controls	Additional controls to lower the overall risk	None, Must, Nice-to-have	Comments

Excel or any other home-grown systems are not really an option since the system validation, the interfacing to other systems, the tracking of actions, etc., limits its use for a sound RBM solution

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